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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,368	01/14/2004	Secondo Dottori	247518US0CONT	2368
22850 7590 12/28/2006 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER SAUCIER, SANDRA E	
			ART UNIT	PAPER NUMBER
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/28/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/756,368

Applicant(s)

DOTTORI, SECONDO

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/23/06.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 57-66 are pending and are considered on the merits.

Claim Rejections - 35 USC § 102

Claims 57-66 remain rejected under 35 U.S.C. 102(a) as being clearly anticipated by Sweeney et al. [AW].

The claims are directed to a method comprising:
adding L-carnitine or an ester of carnitine to a platelet concentrate to form a mixture and suspending the platelet concentrate in the mixture.

The intent of the claimed methods is the suppression of bacterial growth or reduction of glycolysis in the platelet concentrate.

Sweeney et al. disclose a method of adding L-carnitine or acetyl-carnitine (5mM) to platelet concentrates and agitating the mixture. This is said to reduce glycolysis in the platelet mixture.

Although the intent of applicant's method is different from the intent of the disclosed method, the subject of the method (platelet concentrate), the one step of adding carnitine or an ester of carnitine in the same concentration are all the same. Thus, the results of the method, suppression of bacterial growth, would reasonably be assumed to be the same as the result claimed.

It is not relevant to the analysis of the claimed method that the reference makes no mention of suppressing bacterial growth. Discovery of a new benefit for an old process does not render the old process patentable. In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because the reference did not have one of applicant's purposes in mind when the (drug was administered) does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999).

See also In re Cruciferous Sprout 64 USPQ2d 1202 Fed. Circuit, where the Federal Circuit upheld a decision that patents licensed to Brassica Protection Products, Inc. are invalid because they are anticipated by the prior art. The patents are for method of growing and eating certain sprouts

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to reduce the level of carcinogens in animals, thereby reducing the risk of developing cancer. Prior art references disclose growing and eating those specific sprouts. The Federal Circuit cited authority for the rule that "a prior art reference may anticipate when the claim limitations not expressly found in the that reference are nonetheless inherent in it." The court said, "While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new."

Claim Rejections - 35 USC § 103

Claims 57-66 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Sweeney et al. [AW] in combination with US 5,747,536 [AA].

The claims are directed to the addition of various esters of carnitine to a blood platelet concentrate.

Sweeney et al. has been explained above.

US 5,747,536 discloses that esters of carnitine other than acetyl ester are known.

The substitution of other esters of carnitine such as butyryl, valeryl, propionyl, isobutyryl for the acetyl ester of carnitine in the method of Sweeney et al. would have been obvious when US 5,747,536 was taken with Sweeney et al. because US 5,747,536 lists various esters of carnitine and also further discloses the addition of carnitine or its derivatives to platelet concentrates. In the absence of evidence to the contrary, the salts and esters of L-carnitine would reasonably be expected to have a similar activity to L-carnitine or acetylcarnitine.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

In view of the papers filed 10/23/06, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The

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inventorship of this application has been changed by the addition of A. Arduini.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

It is noted in the declaration that under 37 CFR §1.131 and signed by the inventors Arduini and Dottori that Sweeney and Blair were merely assistants carrying out experiments. However, the last author of the cited Sweeney et al. publication, J. Petrucci still remains as an "other" and thus the reference is still applicable against the claims at this time.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

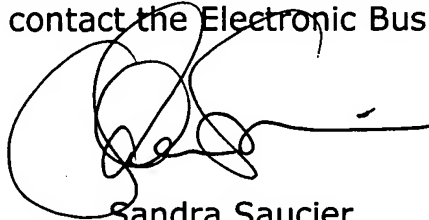
To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is Monday through Friday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sandra Saucier', is written over the printed name.

Sandra Saucier
Primary Examiner
Art Unit 1651
December 15, 2006



DOCKET NO.: 247518US0CONT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: :
SECONDO DOTTORI : ATTN: APPLICATIONS DIVISION
SERIAL NO.: 10/756,368 :
FILED: JANUARY 14, 2004 :
FOR: SUPPRESSION OF BACTERIAL GROWTH IN PLASMA BY ADDITION OF L-
CARNITINE, OR ESTERS OR SALTS THEREOF

*Approved.
MOW*

PETITION UNDER 37 C.F.R. §1.48(a)

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

The undersigned Petitioner herein requests that the inventorship of the above-referenced application be corrected to add Arduino Arduini as an inventor. The inventors in this case are Secondo Dottori and Arduino Arduini.

In accordance with 37 C.F.R. §1.48(a), enclosed is: a statement from each person who is added or deleted as an inventor that the inventorship error occurred without any deceptive intention on his part; a declaration under 37 C.F.R. §1.63 executed by the actual inventors; the written consent of the assignee, SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.; and the fee set forth in 37 CFR §1.17(i).

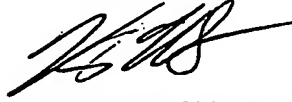
10/25/2006 MBERHE 00000037 10756368
03 FC:1464 130.00 OP

Consequently, it is respectfully requested that this petition be GRANTED.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

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